Section 5: 510(k) Summary

Category	Comments
Sponsor:	Breathe Technologies 175 Technology Drive, Suite 100 Irvine, CA 92618 Tel: 949-988-7700
Correspondent Contact Information:	Craig Coombs President Coombs Medical Device Consulting, Inc 1193 Sherman St. Alameda, CA 94501 Office: 510.337.0140 Fax: 510.337.0416
Device Common Name:	CPAP System
Device Classification Regulation & Name:	21 CFR 868.5905 Ventilator, Non-Continuous (Respirator)
Device Classification & Product Code:	Class II, BZD
Device Proprietary Name:	Breathe CPAP System

Predicate Device Information:

Predicate Device:	XT1 CPAP Model 9S-005
Predicate Device Manufacturer:	Apex Medical Corporation
Predicate Device Premarket Notification #	K070609
Predicate Device Common Name:	CPAP
Predicate Device Classification & Name:	21 CFR 868.5905
Predicate Device Classification & Product Code:	Class II BZD

Reference Device Information:

Predicate Device:	InnoMed IT Nasal Mask
Predicate Device Manufacturer:	InnoMed Technologies
Predicate Device Premarket Notification #	K050171
Predicate Device Common Name:	Ventilator, continuous non-life supporting (accessory to)
Predicate Device Classification & Name:	21 CFR 868.5905
Predicate Device Classification & Product Code:	Class II BZD

b. Date Summary Prepared
4 January 2013

c. Description of Device
The Breathe Technologies™ CPAP system is an AC powered Continuous Positive Airway Pressure (CPAP) device that delivers a physician prescribed pressure during the inspiratory phase and expiratory phases to help maintain airway patency during sleep for patients with obstructive sleep apnea (OSA).

The Breathe CPAP System consists of a programmable, microprocessor controlled, flow generator (i.e., blower) and a Nasal Pillows Mask. The flow generator generates CPAP from room air to the patient and transmits it via the attached Nasal Pillows Mask. The end of the patient circuit is a nasal pillows interface which is worn on the nose. The nasal interface is held in place with standard headgear.

d. Intended Use
The continuous positive airway pressure (CPAP) System is indicated for the treatment of obstructive sleep apnea (OSA) in patients > 66lb (30 kg). The Breathe CPAP System is intended for single-patient re-use in the home environment.

e. Comparison to Predicate Device
The Breathe Technologies CPAP is substantially equivalent in Intended Use, Indications for Use, technology, design, materials, physician or patient use, and energy source to the predicate Apex Medical XTI CPAP Model 9S-005 (K070609) with the InnoMed IT Nasal Mask (K050171).

The testing described below demonstrates that the differences in the devices do not raise any unresolved issues of safety or efficacy.

Breathe Technologies concludes that the devices are substantially equivalent.

f. Summary of Supporting Data
Biocompatibility data demonstrates that the device is in compliance with ISO 10993-1 (2009) Biological evaluation of medical devices -- Part 1: Evaluation and testing

The Breathe CPAP System is compliant with the following Standards and Guidance:

- FDA Draft Reviewer Guide for Ventilators (July 1995)
- ASTM F1246-91 (2005), Standard Specification for Electrically Powered Home Care Ventilators
- IEC 60601 – 1 (1988), Amendment 1 (1991-11), Amendment 2 (1995): Medical electrical equipment – General Requirements for Safety.
- ANSI/AAMI/IEC 60601-1-2 (2007), Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 17, 2013

Breathe Technologies
C/O Mr. Craig Coombs
President
Coombs Medical Devices Consulting, Incorporated
1193 Sherman Street
ALAMEDA CA 94501

Re: K130037
Trade/Device Name: Breathe CPAP System
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: April 15, 2013
Received: April 18, 2013

Dear Mr. Coombs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer -S for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number (if known): K130037

Device Name: Breathe CPAP System

Indications for Use:

The continuous positive airway pressure (CPAP) System is indicated for the treatment of obstructive sleep apnea (OSA) in patients > 66lb (30 kg). The Breathe CPAP System is intended for single-patient re-use in the home environment.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K130037